

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW -I

ANTIMICROBIAL PROGRAM BRANCH

IN: 3/12/97 OUT: 4/22/97

Reviewed by Michael Nieves Date 4/22/97  
LAN Code 8383-3.497  
EPA Reg. No. or File Symbol 8383-3  
EPA Petition or EUP No. None  
Date Division Received 3/26/96  
Type Product Hospital Disinfectant  
MRID No(s) 439651-1  
Product Management Team PM 32  
Product Name Permacide Brand (Ristex) Germicidal Detergent  
Company Name Sporicidin International

Submission Purpose:

The registrant has submitted efficacy data against Infectious bronchitis virus (Coronavirus), Canine parovirus and Cytomeglavirus and proposed labeling.

Type Formulation Liquid

Active Ingredients(s)

Phenol.....	1.41%
Borax.....	.47%
Sodium phenate.....	.24%

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200.0     **Introduction:**

200.1     **Uses:**

Hospital Disinfectant

200.2     **Background Information:**

The registrant has submitted efficacy data against Infectious bronchitis virus (Coronavirus), Canine parovirus and Cytomeglavirus and proposed labeling.

200.3     **Factors Affecting Amount/Type of Data Required:**

None

201.0     **Data Summary**

None

201.1     **Abstract of Test Reports:**

None

201.2     **Brief Description of Tests:**

"Virucidal Effectiveness Test" by Cynthia Kay Osbourne of MicroBioTest, 14280 Sullyfield Circle, Chantilly, VA 22021, dated December 18, 1995, MRID No. 439651-01.

201.3     **Data Summaries**

None

201.4     **Other Summarized Results:**

See Recommendations under 202.0.

202.0      Recommendations

202.1      Efficacy Supported By The Data:

"Virucidal Effectiveness Test" by Cynthia Kay Osbourne of MicroBioTest, 14280 Sullyfield Circle, Chantilly, VA 22021, dated December 18, 1995, MRID No. 439651-01.

The submitted efficacy data appear adequate to support effectiveness of the product as a virucide when used against Infectious bronchitis virus (Coronavirus) ATCC VR-22, Canine parvovirus ATCC-VR 953 and Cytomegalavirus ABI Lot 83-004 Strain AD 169 when used undiluted on hard, non-porous, inanimate, environmental surfaces in the presence of 5% blood serum for a contact time of ten minutes at 20pC.

203.0      Labeling:

The proposed labeling is UNACCEPTABLE. The registrant failed to submit the first page of a two page product label. Specifically, the FRONT PANEL of the product label is missing. A label review cannot be completed until the complete label is submitted.